Medtronic, Inc.
7000 Central Avenue N.E.
Minneapolis, MN 55432 USA
www.medtronic.com

tel 612-514-3409
fax 612-514-6459
chuck.swanson@medtr...

Medtronic

Charles H. Swanson
Vice President, Chief Quality and Regulatory Officer

December 29, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 10-61
Rockville, MD 20852

Re: Draft Guidance for Industry on Financial Disclosure by Clinical Investigators (Docket No. 99D-4396)

Dear Sir or Madam:

Medtronic, Inc., submits the following comments in response to FDA's notice announcing the availability of, "Draft Guidance for Industry on Financial Disclosure by Clinical Investigators." [63 Federal Register 57640, October 26, 1999] Medtronic, Inc., headquartered in Minneapolis, is the world's leading medical technology company, specializing in implantable and interventional therapies that restore health, extend life and alleviate pain. Medtronic, Inc.'s operations are primarily focused on providing therapeutic, diagnostic and monitoring systems for cardiac rhythm management, cardiovascular, neurological, and spinal markets that in 1999 benefited over 1.5 million patients worldwide.

Medtronic, Inc. appreciates FDA's effort to clarify the complex rule on Financial Disclosure by Clinical Investigators and is grateful for the opportunity to comment on this guidance document. In general, we feel the information presented in this guidance has resulted in needed clarification.

Medtronic would also like to acknowledge our support of the comments submitted by the Health Industry Manufactures Association (HIMA) on this guidance document. We request that the FDA consider the following suggestions to further add clarity to this document:

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Question Number 5 – Definition of a Sponsor

Additional clarification is suggested to define financial disclosure requirements for clinical studies operated by the government that manufacturers do not control. Medtronic is concerned that based on the financial disclosure regulations, FDA may interpret a device manufacturer, such as Medtronic, to be a "sponsor" in a study conducted by a government agency such as the National Institutes of Health (NIH). The use of data from government-sponsored studies by manufacturers in support of Premarket Approval applications is well demonstrated. Examples of such government run studies include MUSTT, MADIT, and AVID.

NIH studies have traditionally been believed to be free of bias because they were conducted by the government and not by an individual company. Individual medical device manufacturers whose devices are used in such NIH studies, but have little or no involvement or control, should not be responsible for the conduct of the study. In addition, it is difficult for a device manufacturer to collect information on studies conducted by third parties. Not having any direct contact with the participants in such a study makes it impractical to collect financial information.

We ask that the FDA clarify this issue by taking the position that a device manufacturer is not a "sponsor" in a government-sponsored clinical trial. Therefore, financial interests of investigators of government-sponsored studies are not relevant to the submission of data. The government agencies conducting such government-sponsored studies are responsible for safeguarding against and addressing potential bias.

Question Number 17 - Investigators Involved in Foreign Studies

Medtronic is concerned that information from some foreign countries may not be available in order for Medtronic to comply with the financial disclosure regulations. The European Community (EC) directive specifies that data which is personal to individuals of the EC may not be transferred to countries which do not have sufficient laws to protect the data. There is potential that the FDA's financial disclosure regulation would be considered as providing inadequate protection under this EC directive. Therefore, it may be a violation of the directive and the enabling local laws in the EC to transmit such information out of the EC. Obviously it is unwise for the FDA to establish a requirement that could induce violation of other countries' laws. Medtronic believes that this guidance document should recognize this difficulty and place upon sponsors only the obligation to make a reasonable effort to obtain financial information from the investigators. If it is not forthcoming, the refusal must be accepted in that it could lead to conflict of the laws of that country.

Question Number 27 – FDA Access to Documents of Financial Disclosure During an Inspection

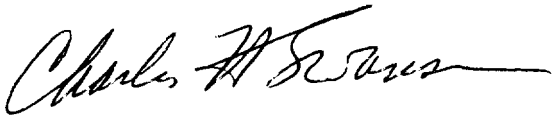
The FDA's response to this question requires clarification. Does the FDA's answer apply to both sponsor and investigator site inspections? There would be little challenge by an investigator to provide summary information to a FDA inspector similar to that provided to the sponsor. However, the FDA must acknowledge the difficulties in obtaining detailed financial information from investigators during a site audit. It is highly likely that some investigators will challenge the authority of the FDA to review confidential financial information. Medtronic is concerned that disputes between investigators and the FDA over FDA's authority to review confidential detailed financial information will delay product approvals. It is recommend that the FDA obtain appropriate legal review and very clearly define the agency's authority.

Need for Additional Clarification

Medtronic believes that this guidance document should provide clarification that financial disclosure is not required for Humanitarian Device Exemptions (HDE). The purpose of an HDE is to treat a very small patient population that is inflicted with a very specific medical disease or condition. By regulation, a manufacturer cannot sell a Humanitarian Use Device (HUD) for more that the cost of research, development, fabrication, and distribution. Because there can be no profit, these devices can not be considered "marketed" in terms of the regulations. In addition, because there is no financial incentive for a manufacture to bias data collected from the use of a HUD, there is no need for disclosure of financial information.

Medtronic appreciates the opportunity to comment on this draft guidance document.

Sincerely,



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Chuck Swanson
Medtronic, Inc.
7000 Central Avenue N.E., #230
Fridley MN 55432
(612)514-3469

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Food and Drug Administration
HFA-305, Rm 1061
5630 Fishers Lane
Rockville MD 20852

(301)827-6880

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